

ETHICON ENDO-SURGERY, INC. and ETHICON)
ENDO-SURGERY, LLC,)

Plaintiffs and Counterclaim-Defendants,

V.

COVIDIEN LP, COVIDIEN SALES LLC, and
COVIDIEN AG,

Defendants and Counterclaim-Plaintiffs.

Civil Action No. 1:16-cv-12556-LTS

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**ETHICON'S SUR-REPLY MEMORANDUM OF LAW IN OPPOSITION TO
COVIDIEN'S MOTION FOR A PRELIMINARY INJUNCTION**

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INTRODUCTION

Having failed to meet its burden of showing that it is entitled to a preliminary injunction in its opening papers, Covidien has submitted lengthy reply papers full of entirely new positions and arguments. Covidien's belated attempts to salvage its deficient motion fail. Claim 1 of the '284 patent, the sole claim at issue, requires, among other things, "a *plurality* of *non-conductive* stop members" that are "configured to maintain a uniform distance between the jaw members." By contrast, the ENSEAL X1 maintains the distance between its jaw members with a *single* pin (not a plurality), and the pin is made of steel, a *conductive* material. [REDACTED]

[REDACTED]

The centerpiece of Covidien's reply papers is a series of previously undisclosed claim construction positions, submitted under the transparent (and incorrect) pretense that they reflect the "plain and ordinary" meaning of the claim. Even if these untimely and improper claim constructions were accepted, Covidien still fails to demonstrate a likelihood of success on the merits. For example, with respect to infringement, Covidien's own witnesses have admitted that there must be contact between the non-conductive stop members and the opposing jaws for the stop members to "maintain a uniform distance" between the jaws as required by claim 1 of the '284 patent. Covidien fails to show that any such contact takes place with the ENSEAL X1.

Regarding the remaining preliminary injunction factors, [REDACTED]

[REDACTED] and the other alleged harms are either not remediable as a matter of law or unsupported by the record. Finally, the public interest and the balance of equities support denying a preliminary injunction, because the harm of an injunction to Ethicon and, more importantly, to the surgeons who have come to prefer the ENSEAL X1 over available alternatives, outweighs any alleged harm to

Covidien in allowing Ethicon to continue selling the device while this litigation is ongoing.

ARGUMENT

I. COVIDIEN HAS NOT SHOWN A LIKELIHOOD OF SUCCESS ON INFRINGEMENT

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

A. Covidien's Claim Construction Theories Are Untimely

In its reply, Covidien seeks to buttress its deficient infringement theories by offering a number of previously undisclosed claim constructions by Dr. Durfee, [REDACTED]

[REDACTED]

[REDACTED] These new claim constructions are both procedurally and substantively deficient.

Covidien's new claim construction arguments are untimely, appearing as they do for the first time on reply. *See, e.g., Johnson v. IndyMac Mortg. Servicing*, 2014 U.S. Dist. LEXIS 55610, at *18 n.14 (D. Mass. Apr. 22, 2014) (declining to consider argument where there was "no reason why [the party] could not have raised this argument in its opening brief"). Contrary to Covidien's mischaracterization of *Millipore Corp. v. W.L. Gore & Assocs.*, No. 11-1453, 2011 U.S. Dist. LEXIS 130206 (D.N.J. Nov. 9, 2011) and *Fair Isaac Corp. v. IBM*, 2006 U.S. Dist. LEXIS 27778, *16-*18 (D. Minn. May 9, 2006), those cases hold that a motion for a preliminary injunction should be denied where, as here, the patentee fails to properly raise a claim

construction dispute. *See Millipore*, 2011 U.S. Dist. LEXIS 130206 at *24-*32; *Fair Isaac*, 2006 U.S. Dist. LEXIS 27778, *16-*18.¹

In any event, as shown below, even if the Court were to consider Covidien's untimely and improper claim constructions, which it should not, they fail to establish infringement.

B. The ENSEAL X1's Non-Conductive Bumps Are Not Configured to Maintain a Uniform Distance Between the Jaw Members

1. Claim 1 Requires Contact Between the Non-Conductive Stop Members and the Opposing Jaw Member

Covidien argues in its reply that claim 1 does not require the non-conductive stop members to "set the gap" between the jaw members. Covidien Reply Mem., Dkt. No. 78, at 4-5. This mischaracterizes Ethicon's argument. As Ethicon made clear, the non-conductive, polymeric bumps on the ENSEAL X1's jaw members do not "maintain a uniform distance" between the jaw members, as required by claim 1, because they do not contact the opposing jaw member. Ethicon Opp. Mem. at 7-9. That the bumps do not "set the gap" is just another way of saying the same thing.

Crucially, there is no dispute that in order to "maintain a uniform distance" between the jaw members, the non-conductive stop members of claim 1 must *contact* the opposing jaw member. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

¹ In *Dentsply Int'l, Inc. v. US Endodontics, LLC*, 2015 WL 12672022 (E.D. Tenn. Nov. 20 2015), cited by Covidien, the court stated that a moving party's failure to address claim construction in its opening brief might warrant a finding that it has not shown a likelihood of success where a court decides the motion on the pleadings. In that case, the court decided to consider the later-provided constructions after holding a full evidentiary hearing, which included claim construction. *Id.*, *6, n.4.

[REDACTED]

[REDACTED] Under any proper construction, claim 1 of the '284 patent requires contact between the plurality of non-conductive stop members and the opposing jaw member, and, as further discussed below, there is no such contact in the ENSEAL X1.

Because contact is required, Covidien's reliance on claims 2 and 9 of the '284 patent to argue implicitly that the claimed non-conductive stop members can be shorter than the gap distance between the jaw members is misplaced. Covidien Reply Mem. at 5-6; Durfee Suppl. Decl., ¶ 10. The '284 patent's specification explains that the claimed non-conductive stop members can be constructed of different materials with different compressive strengths, and therefore "may have to be dimensioned differently from one another material to achieve the same gap distance or desired result." Ginsberg Decl., Dkt. No. 65, Ex. 4 ('284 patent) at 12:47-13:3. Claim 2 thus contemplates stop members that have different heights, but that compress different amounts so that they all contact the opposing jaw member when the device is closed. Claim 9 requires the distance that *each* stop member may protrude from the inner facing surface to be at a specifically claimed amount. Neither of these claims supports Covidien's argument that the stop members are not required to contact the opposing jaw member in order to maintain a uniform distance. Covidien's own expert concedes this point. Ginsberg Suppl. Decl., Ex. 1 (Durfee Tr.) at 268:1-276:18; 98:17-99:16.

2. The Non-Conductive Bumps in the ENSEAL X1 Do Not Contact the Opposing Jaw Member

Covidien fails to prove that the non-conductive, polymeric bumps in the ENSEAL X1 contact the opposing jaw member. [REDACTED]

[REDACTED] Covidien's contention that "the forces exerted during surgery" may lead to contact is not remotely established by the record. Covidien Reply Mem. at 5-6.

As a preliminary matter, Covidien's assertion that the space between the ENSEAL X1's non-conductive bumps and the opposing jaw member is "miniscule" (Covidien Reply Mem. at 5) is highly misleading. All dimensions of this precision surgical device are small in absolute terms. But, in relative terms, the relevant dimensions are large. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] That is not a "miniscule" difference.

Covidien speculates that "squeezing" and torsional forces allegedly experienced during surgery would cause the ENSEAL X1's bumps to contact the opposing jaw. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Moreover, as Dr. Joseph Amaral, an Ethicon surgeon familiar with ENSEAL X1, explains, in order for the device to operate for its intended purpose (i.e., to cut and

seal tissue), there must be enough space for the jaws to open and close such that there can be no substantial compressive forces acting on the jaws. Amaral Decl., ¶¶ 9 and 12; see also Ginsberg Suppl. Decl., Ex. 5 (Frye Tr.) at 75:22-25.

[REDACTED]

[REDACTED]

[REDACTED] Covidien's infringement case suffers from a total failure of proof.

3. Purported Compression During Surgery Would Not Create a "Uniform" Distance Between the ENSEAL X1 Jaw Members

Dr. Durfee's "squeezing" theory creates a second problem for Covidien. The alleged squeezing would result in a non-uniform distance between the jaw members, not a "uniform" distance as required by claim 1 of the '284 patent. Ethicon Opp. Mem. at 10; Leinsing Decl., ¶¶ 44-52. Covidien's response to this point is confused. Covidien Reply Mem. at 6-8. To be clear, Ethicon does not dispute that the gap between the ENSEAL X1 opposing jaw members is intended to be the same. But because this gap is maintained by a single, distal steel pin, and not by the non-conductive bumps on the lower jaw, the ENSEAL X1 does not meet this limitation.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Dr. Durfee apparently was unaware that such a uniformity argument was expressly disclaimed by the applicants themselves during prosecution of the parent to the '284 patent. Leinsing Decl., ¶¶ 48-51; *id.* Ex. 6 at 14-15. Notably, Dr. Durfee acknowledged that he did not consider the parent prosecution history when he submitted his original declaration. Ginsberg Suppl. Decl., Ex. 1 (Durfee Tr.), 237:6-10; 304:13-306:9. In any event, where one or more of the non-conductive bumps are compressed against the opposing jaw, the resulting gap would necessarily be *non-uniform*. See Leinsing Decl., ¶¶ 46-47.

C. The ENSEAL X1's Distal Steel Pin Is Conductive

Having admitted that the distal steel pin on the ENSEAL X1 conducts electricity

[REDACTED]

[REDACTED]

(Ginsberg Suppl. Decl., Ex. 1 (Durfee Tr.), 177:21-180:16; 361:9-25), and in a transparent attempt to salvage an infringement position, [REDACTED]

[REDACTED] There simply is no support for this concocted interpretation of "plain and ordinary meaning." Leinsing Decl., ¶ 56; Ethicon Opp. Mem. at 11-13.

D. The ENSEAL X1 Does Not Have Stop Members That Are "Disposed Along The Same Plane" or "Along the Length of the Seal Surfaces"

At his first deposition, Dr. Durfee testified that the "disposed along the same plane on the seal surface" limitation "has to do with the bottom part of the stop members where they start" or how the stop members are anchored even though the claim refers to the "seal surface." Ginsberg Suppl. Decl., Ex. 1 (Durfee Tr.), 87:18-88:6; 89:10-21. Ethicon addressed this argument by showing that, even if Dr. Durfee's position was accepted, the bottom parts of the ENSEAL X1's purported "stop members" are not on the same plane. Ethicon Opp. Mem. at 13-14; Leinsing Decl., ¶¶ 71-74; Ginsberg Suppl. Decl., Ex. 1, (Durfee Tr.), 404:15-405:1. [REDACTED]

This new and improper construction, which clearly is not the "plain and ordinary meaning," should be rejected. As Dr. Durfee acknowledges, the claim language requires that the plurality of stop members be "disposed along the same plane *on the seal surface with respect to one another*." Ginsberg Suppl. Decl. Ex. 1 (Durfee Tr.), 410:7-411-1. Stop members that do not

start or stop along the same plane cannot be said to be disposed along the same plane on the seal surface with respect to one another. Dr. Durfee's new interpretation would improperly read this phrase out of the claim. *Digital-Vending Servs. Int'l, LLC v. Univ. of Phoenix, Inc.*, 672 F.3d 1270, 1275 (Fed. Cir. 2012).⁴

E. The ENSEAL X1 Is Not an "Endoscopic" Device

The preamble of claim 1 calls for an "endoscopic bipolar forceps." Covidien cites no case holding that a preamble should be ignored where, as here, it is repeatedly referred to throughout the specification to describe the claimed invention. Ethicon Opp. Mem. at 14-15. Covidien also fails to prove that the ENSEAL X1 device, which is indicated only for open procedures, is an endoscopic device.⁵ Covidien's own physician witness, Dr. Kris Gaston, testified that he is not aware of any endoscopic procedure for which the ENSEAL X1 device would be used. Ginsberg Suppl. Decl., Ex. 7 (Gaston Tr.), 16:18-18:13.

II. COVIDIEN CANNOT PROVE A LIKELIHOOD OF SUCCESS ON VALIDITY

Citing two cases where the PTAB's decision to institute IPR proceedings contributed to the *denial* of motions for preliminary injunction, Covidien contends that this Court should defer to the PTAB's decision even though it has no estoppel effect. *Id.* at 2-3. Neither of the cited cases

⁴ Covidien's argument that the ENSEAL X1's stop members are "disposed along the length of the seal surfaces" (Covidien Reply Mem. at 10) also contradicts its prior positions. During prosecution, the applicants for the '284 patent argued that the Eggers prior art reference did not meet this element because its stop members were not "disposed at the proximal *end*" of such surface. *See* Leinsing Decl. at ¶ 75 and Ex. 7 (emphasis added). (Dr. Durfee makes a similar argument in attempting to distinguish Eggers in connection with validity. Durfee Suppl. Decl. at ¶ 55.) In light of this statement, Covidien's argument that the claim does not require stop members on the proximal "edge" fails. As with Eggers, the non-conductive bumps on the ENSEAL X1 do not extend to the "proximal end" of the seal surface. Leinsing Decl., ¶ 27.

⁵

[REDACTED]

supports Covidien's position. A preliminary injunction should be denied whenever there is a "substantial question" of validity. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001). A substantial question exists here.

Indeed, Covidien *concedes* that the PTAB made a mistake. The Eggers prior art reference discloses a device with a uniform distance between jaw members along the length thereof when tissue is disposed between the opposing jaw members. Ethicon Opp. Mem. at 20-21; Leinsing Decl., ¶¶ 80, 94. This can be seen clearly in Fig. 26, which the PTAB failed to notice or correctly interpret. *Id.* at ¶ 112. Dr. Durfee admitted that the gap distance in this figure "*does appear to be uniform.*" Ginsberg Suppl. Decl. Ex. 1 (Durfee Tr.), 422:12-423:8 (emphasis added); *see also id.* at 421:11-422:11 (acknowledging that the PTAB does not discuss Fig. 26); Durfee Suppl. Decl. at ¶ 53.

Nonetheless, [REDACTED]
[REDACTED] Durfee Suppl. Decl., ¶ 54. But because Eggers discloses "substantially flat tissue grasping surfaces" with matching spacers of a uniform thickness mounted thereto, the sealing surface area beyond the insulative spacers still maintains a substantially uniform gap distance when the spacers come together during use. Leinsing Decl., ¶¶ 110-11.⁶ The bowing disclosed in Eggers does not change the fact that there is uniform gap between its jaws, because it is affected outside the jaw area. Leinsing Decl., ¶ 111.

[REDACTED]

⁶ [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED] Dr. Durfee

conceded that the island of insulation disclosed by Fox could create a uniform gap along the jaw members and one could put the island of insulation on any of the embodiments in Fox. Ginsberg Suppl. Decl., Ex. 1 (Durfee Tr.), 420:20-421:1; 430:9-16. Finally, Dr. Durfee conceded that (i) his opinion that replacing the teeth disclosed in Fox with the insulative spacers disclosed in Eggers could affect the combined device's ability to seal tissue and achieve hemostasis was based on speculation, and (ii) Eggers actually provides the motivation to make such modification. *Id.* at 430:19-431:17.

As the foregoing demonstrates, there is, at a minimum, a "substantial" question as to the validity of claim 1 of the '284 patent despite the PTAB's decision.

III. COVIDIEN CANNOT ESTABLISH IRREPARABLE HARM

A.

Although Covidien suggests that alleged lost sales of its competitive device, LigaSure Impact (Covidien Reply Mem. at 11), constitute irreparable harm, [REDACTED]

[REDACTED]

[REDACTED] *See, e.g., Eli Lilly &*

Co. v. American Cyanamid Co., 82 F.3d 1568, 1578-79 (Fed. Cir. 1996) (finding no irreparable

harm where money damages were a sufficient remedy and "calculating lost profits would be a relatively simple task").

B. Covidien's Alleged Harm from "Pull Through" Sales of Unrelated Products Are Not Remediable by Patent Law and Can Be Quantified

The possible loss of "pull-through" sales does not warrant granting a preliminary injunction. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] And for good reason. Although Federal Circuit precedent allows for recovery for sales of unpatented products that are functionally related to a patented product, it "has *not* extended liability to include items that have essentially no functional relationship to the patented invention and that may have been sold with an infringing device only as a matter of convenience or business advantage." *Am. Seating Co. v. USSC Group, Inc.*, 514 F.3d 1262, 1268 (Fed. Cir. 2008) (emphasis added).

To be sure, Covidien is correct that it would have great difficulty showing that any claimed losses of customers and their associated "pull-through" sales are *caused* by the ENSEAL X1, but that is attributable to the weakness of its argument. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

These arguments do not support Covidien's position, however, because the lack of a causal connection between the alleged harm and the alleged infringement bars injunctive relief as well as lost profits. *See Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1375 (Fed. Cir. 2012); *infra* at 13-14. If lost "pull through" sales were remediable and caused by infringement, which they are not, there is no reason they could not be quantified, [REDACTED]

C. Covidien's Other Claimed Harms are Unsupported and Speculative

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

IV. THERE IS NO NEXUS BETWEEN THE ALLEGED INFRINGEMENT AND THE CLAIMED HARM

In addressing nexus, Covidien's reply focuses on the alleged importance of jaw gap distance to sealing performance. Covidien Reply Mem. at 13-14. But any connection between jaw distance and sealing does not establish a nexus between the patented features and the alleged irreparable harm. Rather, Covidien must prove that the alleged inventions of the '284 patent

represent *improvements* over previous devices, and show "why *those improvements* are factors that impact physicians' decisions to use" the ENSEAL X1. *Integra LifeSciences Corp. v. Hyperbranch Med. Tech., Inc.* No. 15-819, 2016 U.S. Dist. LEXIS 124152, at *74 (D. Del. Aug. 12, 2016) (emphasis in original); see *Hydrodynamic Indus. Co. Ltd. v. Green Max Distribs., Inc.*, No. 2:12-cv-05058, 2014 U.S. Dist. LEXIS 80336, at *5 (C.D. Cal. June 16, 2014) (nexus turned on how patented features "improved upon the prior art"). Surgical instruments with a uniform jaw gap were known in the art long before the '284 patent issued. Leinsing Decl., ¶¶ 90-101. Covidien has not shown that any improvements embodied in the patent drive demand.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

V. THE EQUITIES AND PUBLIC INTEREST FAVOR ETHICON

Citing no case law, Covidien contends that the balance of the equities weighs in its favor,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The public interest also favors permitting Ethicon to continue selling the ENSEAL X1 while this case is being litigated. Although Covidien points out that medical needs can be satisfied without the ENSEAL X1 (Covidien Reply Mem. at 15), it cannot dispute that numerous surgeons prefer it. *See, e.g.*, Frye Decl. ¶¶ 6-14; Hill Decl. ¶¶ 5-11; Mainous Decl. ¶¶ 6-10, and Werner Decl. ¶¶ 6-9. The public interest supports allowing surgeons to choose the device they prefer. *See Datascope Corp. v. Kontron, Inc.*, 786 F.2d 398, 401 (Fed. Cir. 1986); *Cordis Corp. v. Boston Scientific Corp.*, 99 F. App'x 928, 935 (Fed. Cir. 2004). Covidien's own physician witness, Dr. Gaston, agreed with this point, Ginsberg Suppl. Decl., Ex. 7 (Gaston Tr.), 27:8-28:13, 43:14-25, and Covidien's economic expert could not deny it, instead testifying that he would "put that back to the [C]ourt," Ginsberg Suppl. Decl., Ex. 8 (Ugone Tr.), 231:5-232:5. The Court should not prevent surgeons having from access to their preferred device, the ENSEAL X1.

CONCLUSION

For the foregoing reasons, Covidien's request for a preliminary injunction should be denied.

Dated: September 1, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

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/s/ Jack I. Siegal
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